UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,348	12/01/2000	Ying-Fei Wei	PF220P1	3638

22195 7590 04/19/2002

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	12

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

esponsive to communication(s) filed on 3/6/02.

his action is **FINAL**.

nce this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in ccordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

rtened statutory period for response to this action is set to expire 3 month(s), or thirty days, ever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause plication to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR (a).

sition of Claims

Claim(s) 1, 13, 17-20, 24, 25-77 is/are pending in the application.

Of the above, claim(s) 1, 13, 17-20, 24, 25 is/are withdrawn from consideration.

Claim(s) ✓ is/are allowed.

Claim(s) 26-77 is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1, 13, 17-20, 24-77 are subject to restriction or election requirement.

cation Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

ty under 35 U.S.C. § 119

knowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

rtified copies not received: _____.

knowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

hment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, 7, 11

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

Part III: Detailed Office Action

Notice: **Effective June 18, 2000**, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

Restriction Requirement:

It is noted that claim 23 is improperly dependent, as a product does not further limit a "method of identifying". As it cannot be determined what the product is, claim 23 is not included in any of the groupings below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15 and 21, drawn to nucleic acids, vectors and cells, classified in class 435, subclass 69.1.

II. Claims 11, 12 and 16, drawn to protein, classified in class 530, subclass 350.

III. Claim 13, drawn to antibodies, classified in class 530, subclass 387.9.

IV. Claim 17, drawn to a method of treatment using protein , classified in class 514, subclass 2.

V. Claim 17, drawn to a method of treatment using nucleic acid, classified in class 514, subclass 44.

VI. Claim 18, drawn to a nucleic acid diagnostic method, classified in class 435, subclass 6.

VII. Claim 19, drawn to a protein diagnostic method, classified in class 435, subclass 7.1.

VIII. Claim 20, drawn to a binding assay, classified in class 436, subclass 501.

IX. Claim 24, drawn to an agonist of the protein of claim 11, classification dependent upon species .

X. Claim 25, drawn to an antagonist of the protein of claim 11, classification dependent upon species .

The inventions are distinct, each from the other because:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 15. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The products of Inventions I and III are separate and distinct, wherein the products are physically and functionally distinct, capable of separate manufacture and use, and wherein the products require separate searches.

The methods of Invention I are separate and distinct from the products of Invention III wherein the products may neither be made by nor used in the methods.

The products of Invention I are separate and distinct from the methods of Inventions IV, VII, and VIII, wherein the products may neither be made by nor used in the methods.

Invention I is related to each of inventions V, VI and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in any of the three patentably distinct methods.

The products of Inventions I, X and XI are separate and distinct, wherein the products are physically and functionally distinct, capable of separate manufacture and use, and wherein the products require separate searches. It is further noted that the products of Inventions II, X and XI are mutually exclusive, and require divergent searches.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being

the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein, or in assays for the identification of agonists or antagonists of the receptor protein.

Invention II is related to each of inventions IV, VII and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein may be used in any of the three patentably distinct methods, or as an antigen for the production of the antibodies of Invention III.

The products of Invention II are separate and distinct from the methods of Inventions V, VI, and IX, wherein the products may neither be made by nor used in the methods.

Inventions IV-IX are drawn to patentably distinct methods. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Therefore, a search and examination of all Invention IV-IX's methods in one patent application would result in an undue burden, since the searches for the Invention IV-IX's methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 37 C.F.R. § 1.48(b) and by the fee required under 37 37 C.F.R. § 1.17(i).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/726348.r
2/5/02